510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K040146

B. Purpose for Submission:
To show substantial equivalence to the predicate device for separation of abnormal hemoglobin fractions by electrophoresis with the use of cellulose acetate supported on Mylar®.

C. Analyte:
Hemoglobin Fractions

D. Type of Test:
Qualitative, Hemoglobin Electrophoresis

E. Applicant:
InterLab Scientific Instruments, srl
Via Rina Monti NN 26 C.A.P. 00155
Rome, ITALY

F. Proprietary and Established Names:
InterLab Acid Hemoglobin Electrophoresis Test System

G. Regulatory Information:

1. Regulation section:
   21 CFR 864.7415
2. Classification:
   Class II
3. Product Code:
   GKA
4. Panel:
   Hematology (81)

H. Intended Use:

1. Intended use(s):
   The InterLab Acid Hemoglobin Electrophoresis Test System a qualitative test system intended for the electrophoretic separation of hemoglobins to confirm the identity of clinically relevant hemoglobins such as A, F, S and C. It is to be used in conjunction with the Interlab Alkaline Hemoglobin Electrophoresis test kit. The Acid Hemoglobin test kit employs cellulose acetate supported on Mylar® as the medium and is for *in vitro* diagnostic use. The test can be automated on the Microtech 672 PC and the Microtech 648 ISO instruments
2. Indication(s) for use:
   The InterLab Acid Hemoglobin Electrophoresis Test System a qualitative test system intended for the electrophoretic separation of hemoglobins to confirm the identity of clinically relevant hemoglobins such as A, F, S and C. It is to be used in conjunction with the Interlab Alkaline Hemoglobin Electrophoresis test kit. The Acid Hemoglobin test kit employs cellulose acetate supported on

Mylar® as the medium and is for *in vitro* diagnostic use. The test can be automated on the Microtech 672 PC and the Microtech 648 ISO instruments.

3. Special condition for use statement(s):
   Not applicable
4. Special instrument Requirements:
   The Cellulose Acetate supported on Mylar® strips are for use on the Microtech 672 PC and the Microtech 648 ISO instruments. These instruments employ the use of a robotic arm that moves the strip to the different stations. The instruments are offered as "open systems" and are considered Class I Exempt based on 21 CFR 862.2485, product code JJN.

I. Device Description:

The InterLab Acid Hemoglobin Electrophoresis Test System provides identification of clinically relevant hemoglobins such as A, F, S and C visually by staining of the separate fractions. The kit contains materials for 24 runs. There are two kits available (SRE164K and SRE158K) providing the ability to run 192 or 288 tests. Each kit contains the following: testing strips, running and soaking buffer, staining solution, destaining solution, and clearing solution. All reagents are ready to use.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Paragon, Beckman Coulter
2. Predicate K number(s):
   K834595
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
	InterLab Acid Electrophoresis Test System	***Paragon Acid Hemoglobin***
Intended Use	Separation of hemoglobins to confirm the identity of clinical relevant hemoglobins such as A,F,S and C.	Same
Method	Electrophoresis	Same
Sample	Hemolyzed separated red blood cells using distilled water	Hemolyzed separated red blood cells using hemolyzing solution
Sample application	Pipetting Station	Same
Results	Visual or quantitated by densitometry	Visual or quantitated by densitometry
Differences		
Item	**Device**	**Predicate**
Support Medium	Cellulose Acetate on Mylar	Agarose Gel
Reagents	Running Buffer	Maleic Acid Buffer

	Staining Solution (**Ponceau red**) Destaining Solution Clearing Solution	**Violet** Stain Solution Hemolyzing Reagent Destaining Solution Required but Not Supplied: Glacial Acidic Acid Methanol Deionized Water
Equipment	Microtech 684 ISO System Microtech 672 PC System	Paragon Electrophoresis System

K. Standard/Guidance Document Referenced (if applicable):

Not provided

L. Test Principle:

The principle of acid hemoglobin electrophoresis is based upon the visualization of specific hemoglobin bands following separation by electrophoresis. Hemolysates made from whole blood patient specimens are placed in separate lanes of a cellulose acetate slide. The major hemoglobin groups (Hb A, C, F and S) are separated by electrophoresis. The migration rate depends on the temperature, pH, ionic force of the solution and proportions of the reactants. After electrophoresis, the slide is processed to remove excess soluble materials through a washing step. Fractionated hemoglobins are stained. The excess of stain is removed by a destaining step. The slides are visually read to identify the bands present.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    - *a. Precision/Reproducibility:*

      Intra-assay

      The intra-assay precision was measured using an acid hemoglobin control (AFSA2) and two different patient samples run in replicates (8 and 12). The patterns were visually inspected and found to be qualitatively identical.

      Inter-assay

      Inter-assay precision was measured using one abnormal control (AFSC) and two different patients run in replicates (3 each) for 10-11 cellulose acetate strips over three-four days. The patterns were visually inspected and found qualitatively identical.
    - *b. Linearity/assay reportable range:*

      Not applicable
    - *c. Traceability (controls, calibrators, or method):*

      Not applicable
    - *d. Detection limit:*

      An abnormal control with known concentration values was serially diluted and run using the InterLab Acid Hemoglobin Electrophoresis Test System. The degree of band visibility showed detection of hemoglobin bands at concentrations greater than 2.4 g/L for HbA, 1.9g/L for Hb F, 1.6 g/L for HbS and 1.54 g/L for HbC.

e. Analytical specificity:
Ineffective centrifugation and/or RBC washing with saline solution will not yield a clear hemolysate. This may result in the presence of a red line at the application point, which is indicative of a poor quality electrophoretic patter**. The Acid Hemoglobin test is not recommended for quantitation of increased levels of HbF**. The point of sample application should not be visible in the pattern. If the application point is present as a line strongly stained, expect a smeared pattern, with poor resolution and substandard focusing of the bands. Deviation from the recommended test procedure may affect the results.

f. Assay cut-off:
Not applicable

2. Comparison studies:
   a. Method comparison with predicate device:
   Comparison studies were performed by visual inspection of the electrophoretic patterns on 71 normal and suspected pathological patients. The InterLab Acid Hemoglobin Electrophoresis Test System demonstrated equivalent band patterns to the predicate with no false negative or false positive bands observed. The study resulted in a 100% agreement.
   b. Matrix comparison:
   Not applicable
3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable
   b. Clinical specificity:
   Not applicable
   c. Other clinical supportive data (when a and b are not applicable):
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   Not applicable

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.